Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002

No.: 7-5/2014/EU/WC-0273

Dated: 18 AUG 2017

To

M/s. Sionc Pharmaceuticals Pvt Ltd,
Plot No. 34A, Road No. 1,
Jawaharlal Nehru Pharma City, Thanam (V),
Parawada (M), Visakhapatnam, A.P-India

SUB: - Written Confirmation of M/s. Sionc Pharmaceuticals Pvt Ltd, Plot No. 34A, Road No. 1, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), Visakhapatnam, A.P, India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b (2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your application submitted to CDSCO, Hyderabad Zone office and the recommendation received from DDC (I), South Zone, Hyderabad, on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) region for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).

2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.

3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.

4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.

5. The Written Confirmation will be withdrawn in the events of non compliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid up to
1	08	12.05.2017	11.05.2020
2	03	12.05.2017	11.05.2020
3	01	18 AUG 2017	11.05.2020

Yours faithfully,

(Dr. G. N Singh)
Drugs Controller General (India)

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : **Annexure-3**
WC-0273

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s. Sionc Pharmaceuticals Pvt Ltd,**
Plot No. 34A, Road PNo. 1,
Jawaharlal Nehru Pharma City, Thanam (V),
Parawada Mandal, Visakhapatnam, A.P -India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Melphalan (EP/USP)	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 11th May, 2020

Signature

Stamp of the authority and date

18 AUG 2017

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated: 12 MAY 2017

No.: 7-5/2014/EU/WC-0273

To

M/s. Sionc Pharmaceuticals Pvt Ltd,
Plot No. 34A, Road No. 1,
Jawaharlal Nehru Pharma City, Thanam (V),
Parawada (M), Visakhapatnam, A.P-India

SUB: - Written Confirmation of M/s. Sionc Pharmaceuticals Pvt Ltd, Plot No. 34A, Road No. 1, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), Visakhapatnam, A.P, India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b (2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your application submitted to CDSCO, Hyderabad Zone office and the recommendation received from DDC (I), South Zone, Hyderabad, on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) region for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).

2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.

3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.

4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.

5. The Written Confirmation will be withdrawn in the events of non compliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid up to
1	08	12 MAY 2017	Three years from the date of issue
2	03	12 MAY 2017	Three years from the date of issue

Yours faithfully,

(Dr. G. N Singh)
Drugs Controller General (India)

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : WC-0273

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s. Sionc Pharmaceuticals Pvt Ltd,**
Plot No. 34A, Road No. 1,
Jawaharlal Nehru Pharma City, Thanam (V),
Parawada Mandal, Visakhapatnam, A.P -India.

2. Manufacturer's licence number: 52/VP/AP/2010/B/R dated 19/11/2010

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

As per List enclosed as Annexure-1

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: 15.06.2016 & 16.06.2016

The Written Confirmation remains valid until: **Three years from the date of issue**

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: **Central Drugs Standard Control Organisation**
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India

Name and function of responsible person: Dr. G.N. Singh,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization * Ministry of Health Family Welfare Government of India *

12 MAY 2017

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure-1

CERTIFICATE NO. : WC-0273

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Sionc Pharmaceuticals Pvt Ltd,
Plot No. 34A, Road No. 1,
Jawaharlal Nehru Pharma City, Thanam (V),
Parawada Mandal, Visakhapatnam, A.P -India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Chlorambucil (IH/EP)	Manufacturing & Packing
2.	Nilutamide (IH/EP)	Manufacturing & Packing
3.	Bendamustine Hydrochloride (IH)	Manufacturing & Packing
4.	Bortezomib (IH)	Manufacturing & Packing
5.	Dimethyl Fumarate (IH)	Manufacturing & Packing
6.	Etacrynic Acid (EP/IH)	Manufacturing & Packing
7.	Decitabine (IH)	Manufacturing & Packing
8.	Diatrizoate Sodium (EP)	Manufacturing & Packing

ITEM(S) Eight (08) ONLY

The Written Confirmation remains valid until: Three years from the date of issue

Signature

Stamp of the authority and date

12 MAY 2017

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure-2

CERTIFICATE NO. : WC-0273

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Sionc Pharmaceuticals Pvt Ltd,
Plot No. 34A, Road No. 1,
Jawaharlal Nehru Pharma City, Thanam (V),
Parawada Mandal, Visakhapatnam, A.P -India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Melphalan Hydrochloride (IH)	Manufacturing & Packing
2.	Clofarabine (IH)	Manufacturing & Packing
3.	Diatrizoate Meglumine (USP)	Manufacturing & Packing

ITEM(S) Three (03) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority on case to case basis to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: Three years from the date of issue

Signature

Stamp of the authority and date

12 MAY 2017

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 16 OCT 2017

No.: 7-5/2014/EU/WC-0273

To

M/s Sionc Pharmaceuticals Pvt. Ltd,
Plot No. 34A, Road No.1,
Jawaharlal Nehru Pharma City, Thanam (V),
Parawada (M), Vishakhapatnam, A.P- India

SUB: - Written Confirmation of M/s Sionc Pharmaceuticals Pvt. Ltd, Plot No. 34A, Road No.1, Jawaharlal Nehru Pharma City, Thanam (V), Parawada (M), Visakhapatnam, A.P- India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-reg.

Sir,

Please refer to your application submitted to CDSCO, Hyderabad Zone office and the recommendation received from DDC (I), Hyderabad Zone on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).

2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.

3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.

4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.

5. The Written Confirmation will be withdrawn in the events of non-compliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non-Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules there under as the case may be.

Please acknowledge the receipt.

S.No.	No. of Products	Date of Issue	Valid up to
1	08	12.05.2017	11.05.2020
2	03	12.05.2017	11.05.2020
3	01	18.08.2017	11.05.2020
4	01	16 OCT 2017	11.05.2020
5	01	16 OCT 2017	11.05.2020

Yours faithfully,

(Dr. G. N Singh)
Drugs Controller General (India)

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure-04

CERTIFICATE NO. : WC-0273

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s Sionc Pharmaceuticals Pvt. Ltd,
Plot No. 34A, Road No.1,
Jawaharlal Nehru Pharma City, Thanam (V),
Parawada (M), Vishakhapatnam, A.P- India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Taurolidine (IH)	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 11th May, 2020

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization * Ministry of Health Family Welfare Government of India *

16 OCT 2017

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure-05

CERTIFICATE NO. :

WC-0273

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s Sionc Pharmaceuticals Pvt. Ltd,**
Plot No. 34A, Road No.1,
Jawaharlal Nehru Pharma City, Thanam (V),
Parawada (M), Vishakhapatnam, A.P- India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Zofenopril Calcium (IH)	Manufacturing & Packing

ITEM(S) One (01) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until: 11th May, 2020

Signature

Stamp of the authority and date

16 OCT 2017

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated 09 JUL 2018

No.: 7-5/2014/EU/WC-0273

To

M/s. Sionc Pharmaceutical Pvt. Ltd.,
Plot No.34A, Road No.01,
Jawaharlal Nehru Pharma City,
Thanam (V), Parawada Mandal,
Visakhapatnam District, Andhra Pradesh, India.

Subject:- Written Confirmation of M/s. Sionc Pharmaceutical Pvt. Ltd., Plot No.34A, Road No.01 Jawaharlal Nehru Pharma City, Thanam (V), parawada Mandal, Visakhapatnam District, Andhra Pradesh, India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your application submitted to CDSCO, Hyderabad Zone office and the recommendation received from DDC(I), Hyderabad Zone on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).

2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.

3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.

4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.

5. The Written Confirmation will be withdrawn in the events of non compliance of Standards.
6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Up to
1	08	12.05.2017	11.05.2020
2	03	12.05.2017	11.05.2020
3	01	18.08.2017	11.05.2020
4	01	16.10.2017	11.05.2020
5	01	16.10.2017	11.05.2020
6	01	09 JUL 2018	11.05.2020

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Annexure-6

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : WC-0273

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s. Sionc Pharmaceutical Pvt. Ltd., Plot No.34A, Road No.01, Jawaharlal Nehru Pharma City, Thanam (V), Parawada Mandal, Visakhapatnam District, Andhra Pradesh, India.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Ferric Citrate IH	Manufacturing & Packing

ITEM(S) One (01) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 11.05.2020

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization * Ministry of Health Family Welfare, Government of India * सत्यमेव जयते

09 JUL 2018

F. No: 7-5/2014/EU/WC-273
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated: 28 MAY 2019

To

M/s Sionc Pharmaceuticals Pvt Ltd.,
Plot No.34A, Road No.01,
Jawaharlal Nehru Pharma City,
Thanam(V),Parawada Mandal,
Vishakapatnam Dist, Andhra Pradesh,India.

Sub: Written Confirmation M/s Sionc Pharmaceuticals Pvt Ltd., Plot No.34A, Road No.01,JNPC, Thanam(V), Parawada Mandal, Vishakapatnam Dist, Andhra Pradesh 531021 INDIA of as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b (2) (b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your application submitted to CDSCO, Hyderabad Zonal office and the recommendation received from DDC (I), Hyderabad Zone on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).

2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.

3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.

4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.

5. The Written Confirmation will be withdrawn in the event of non-compliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of issue	Valid up to
01	08	12.05.2017	11.05.2020
02	03	12.05.2017	11.05.2020
03	01	18.08.2017	11.05.2020
04	01	16.10.2017	11.05.2020
05	01	16.10.2017	11.05.2020
06	01	09.07.2018	11.05.2020
07	03	28 MAY 2019	11.05.2020
08	08	28 MAY 2019	11.05.2020

Yours faithfully,

(Dr.S.Eswara Reddy)
Drugs Controller General (India).

o/c
17.05.19
17.5.19

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : Annexure- 07
WC 273

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s Sionc Pharmaceuticals Pvt Ltd.,
Plot No.34A, Road No.01,
Jawaharlal Nehru Pharma City,
Thanam(V), Parawada Mandal,
Vishakapatnam Dist,
Andhra Pradesh,India

List of APIs:

S. No.	Active substance (s)	A :tivity(ies)
1.	D-Pencillamine IH	Manufacturing & Packing
2.	Trifluridine IH	Manufacturing & Packing
3.	Temozolamide IH	Manufacturing & Packing

ITEM(S) Three (03) Only

The Written Confirmation remains valid until: 11.05.2020

Signature

Stamp of the authority and date

28 MAY 2019

o/c

17.05.19

17-5-19

17/05/19

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure- 08

CERTIFICATE NO. : WC-0273

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. **Name and address of site: M/s Sionc Pharmaceuticals Pvt Ltd.,**
Plot No.34A, Road No.01,
Jawaharlal Nehru Pharma City,
Thanam(V),Parawada Mandal,
Vishakapatnam Dist,
Andhra Pradesh, India.

List of APIs:

S. No.	Active substance (s)	Activity(ies)
1.	Acitretin USP	Manufacturing & Packing
2.	Aminocaproic Acid IH	Manufacturing & Packing
3.	Frovatriptan Succinate IH	Manufacturing & Packing
4.	Regadenoson IH	Manufacturing & Packing
5.	Plerixafor IH	Manufacturing & Packing
6.	Palbociclib IH	Manufacturing & Packing
7.	Vigabatrin IH	Manufacturing & Packing
8.	Chlorozoxane IH	Manufacturing & Packing

ITEM(S) Eight (08) Only

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture or sale in India

The Written Confirmation remains valid until: 11.05.2020.

Signature

Stamp of the authority and date

28 MAY 2019

o/c 17.05.19

17.5.19